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| APPLICATION NO.                                  | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|----------------|----------------------|-------------------------|------------------|
| 10/035,783                                       | 12/24/2001     | Michael Graupe       | 1016US                  | 3968             |
| 7.   | 590 11/06/2002 |                      |                         |                  |
| Celera, An Applera Corporation Business          |                |                      | EXAMINER                |                  |
| 180 Kimball Way<br>South San Francisco, CA 94080 |                |                      | SHIAO, REI-TSANG        |                  |
|  |                |                      | ART UNIT                | PAPER NUMBER     |
|  |                |                      | 1626                    | ./               |
|  |                |                      | DATE MAILED: 11/06/2002 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

| Application No. | Applicant(s)  |
|-----------------|---------------|
| 10/035,783      | GRAUPE ET AL. |
| Examiner        | Art Unit      |
| Robert Shiao    | 1626          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply** 

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE  $\underline{1}$  MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

| <ul> <li>Any reply</li> </ul>   | o reply within the set or extended period for it<br>received by the Office later than three monta<br>atent term adjustment. See 37 CFR 1.704(b | hs after the mailing date of this co                                 | mmunication, even if timely filed, may reduce any   |  |  |
|---|--|--|---|--|--|
| Status  |  |  |   |  |  |
| 1)⊠ R   | Responsive to communication(s  | ) filed on <u>Application re</u>                                     | <u>ceived on 12/24, 2001</u> .  |  |  |
|   | his action is FINAL.   | 2b)⊠ This action is  |   |  |  |
| cl  | losed in accordance with the p   | tion for allowance exce <sub>l</sub> ractice under <i>Ex parte</i> 0 | ot for formal matters, prosecution as to the merits is<br>Quayle, 1935 C.D. 11, 453 O.G. 213.           |  |  |
| Disposition   |  |  |   |  |  |
| •   | aim(s) 1-31 is/are pending in t  |  |   |  |  |
| 4a)   | ) Of the above claim(s) i  | s/are withdrawn from co  | onsideration.   |  |  |
| 5)∏ Cla   | aim(s) is/are allowed.   |  |   |  |  |
| 6)∏ Cla   | aim(s) is/are rejected.  |  |   |  |  |
| 7)∏ Cla   | aim(s) is/are objected to  | ) <b>.</b>   |   |  |  |
| 8)⊠ Cla   | aim(s) <u>1-31</u> are subject to restr  | iction and/or election re  | quirement.  |  |  |
| Application   | Papers   |  |   |  |  |
| · —   | e specification is objected to by  |  |   |  |  |
| -   | e drawing(s) filed on is/a   |  |   |  |  |
|   | • •  |  | s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |
| 11)∐ The  | e proposed drawing correction  | filed on is: a)☐ a   | approved b)☐ disapproved by the Examiner.   |  |  |
| lf  | f approved, corrected drawings are   | e required in reply to this C  | Office action.  |  |  |
| 12) The   | e oath or declaration is objecte   | d to by the Examiner.  |   |  |  |
| Priority und  | der 35 U.S.C. §§ 119 and 120   |  |   |  |  |
| 13) 🗌 Ad  | cknowledgment is made of a cl  | aim for foreign priority u   | nder 35 U.S.C. § 119(a)-(d) or (f).   |  |  |
| a)  | All b) Some * c) None €  | of:  |   |  |  |
| 1.  | 1. Certified copies of the priority documents have been received.  |  |   |  |  |
| 2.[   | 2. Certified copies of the priority documents have been received in Application No   |  |   |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). |  |  |   |  |  |
|   | e the attached detailed Office a   |  |   |  |  |
| 14) <u></u> Ack   | knowledgment is made of a claim  | m for domestic priority  | under 35 U.S.C. § 119(e) (to a provisional application).  |  |  |
| a) [<br>15)[] Ack   | ☐ The translation of the foreigr<br>knowledgment is made of a cla  | language provisional a<br>im for domestic priority                   | pplication has been received.<br>under 35 U.S.C. §§ 120 and/or 121.                                     |  |  |
| Attachment(s)   | )  |  |   |  |  |
| 2) Notice of  | of References Cited (PTO-892) of Draftsperson's Patent Drawing Revie<br>tion Disclosure Statement(s) (PTO-144                                  |  | 4) Interview Summary (PTO-413) Paper No(s) 5) Notice of Informal Patent Application (PTO-152) 6) Other: |  |  |

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## **DETAILED ACTION**

- **1.** This application claims benefit of the provisional application 60, 257,603 with a filing date 12/22/2000.
- 2. Claims 1-31 are pending in the application.

## Election/Restrictions

- 3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 8-9, 13-15, and 1-7, in part, are drawn to compounds or pharmaceutical compositions, classified in class 558, subclass various, depending on compounds election, wherein X<sub>1</sub>, R<sup>3</sup>, and R<sup>4</sup> substitutents are non-heterocyclic moieties. If this group is elected, a further election of a single disclosed compounds of the group is also required.
    Generic claim 28, in part, which is related to pharmaceutical compositions, reading on the elected group can be prosecuted together with the election to the extend of the elected compounds.

Generic claims 29-30, which are related to methods for use, can be prosecuted together with the election to the extend of the elected compounds upon election of a single disclosed disease associated with inhibition of Cathepsin S.

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Generic claim 31, wherein the process is applicable to making of elected compounds, can be prosecuted together with the election to the extend of the elected compounds.

II. Claims 10-12,16-18, 19-21, 22-24, and 1-7, in part, are drawn to compounds or pharmaceutical compositions, classified in class 544-548, subclass various, depending on compounds election, wherein X<sub>1</sub>, R<sup>3</sup>, and R<sup>4</sup> substitutents are oxazol, morpholine, pyrrole, pyridine, oxadiazol, piperidine etc. (complete listings is not made). If this group is elected, a further election of a single disclosed compound of the group is also required.

Generic claim 28, in part, which is related to pharmaceutical compositions, reading on the elected group can be prosecuted together with the election to the extend of the elected compounds.

Generic claims 29-30, which are related to methods for use, can be prosecuted together with the election to the extend of the elected compounds upon election of a single disclosed disease associated with inhibition of Cathepsin S.

Generic claim 31, wherein the process is applicable to making of elected compounds, can be prosecuted together with the election to the extend of the elected compounds.

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Claims 25-27, and 1-7, in part, are drawn to compounds or pharmaceutical compositions, classified in class 540-548, subclass various, depending on compounds election, wherein X<sub>1</sub>, R<sup>3</sup>, and R<sup>4</sup> substitutents azepane, morpholine, or azetidine etc (complete listings is not made). If this group is elected, a further election of a single disclosed compound of the group is also required.

Generic claim 28, in part, which is related to pharmaceutical compositions, reading on the elected group can be prosecuted together with the election to the extend of the elected compounds.

Generic claims 29-30, which are related to methods for use, can be prosecuted together with the election to the extend of the elected compounds upon election of a single disclosed disease associated with inhibition of Cathepsin S.

Generic claim 31, wherein the process is applicable to making of elected compounds, can be prosecuted together with the election to the extend of the elected compounds.

Or II or III, is drawn to compounds, classified in class 558, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of the group is also required.

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Generic claim 28, in part, which is related to pharmaceutical compositions, reading on the elected group can be prosecuted together with the election to the extend of the elected compounds.

Generic claims 29-30, which are related to methods for use, can be prosecuted together with the election to the extend of the elected compounds upon election of a single disclosed disease associated with inhibition of Cathepsin S.

Generic claim 31, wherein the process is applicable to making of elected compounds, can be prosecuted together with the election to the extend of the elected compounds.

The inventions listed as Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding special technical features for the following reasons:

Inventions of Group I, II, III, and IV are independent and distinct because compounds of each group differ in elements, bonding arrangement and chemical property to such an extend that a reference anticipating compounds of any one group would not render another group obvious. The search for each group of compounds is not required for another group of compounds and is not coextensive of each other. Therefore separate search and examination must be required.

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Different search considerations are involved with each of the group listed above and would impose an undue burden on the Examiner and the Patent Office's resources if unrestricted.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different elements and the search required for Group I, for example, is not required for Group II or group IV, restriction for examination purposes as indicated is proper.

**4.** Applicants are required to elect a single disclosed species from whichever group is ultimately elected.

Applicants are advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (703) 308-4002. The examiner can normally be reached on 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K Mckane can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert Shiao Patent Examiner Art Unit 1626 Joseph K. McKane Supervisory Patent Examiner Art Unit 1626

October 31, 2002